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APPLICATION NO. 313	FILING DATE 30/97	WR IF FIRST NAMED INVENTOR	ATTORNEY DOCKET NO 3
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SHI EXAMINER

ART UNIT 35

PAPER NUMBER

06/05/00

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No. <b>08/886,313</b>	Applicant(s) <b>WRIGHT ET AL.</b>
	Examiner <b>Mark L. Shibuya</b>	Group Art Unit <b>1635</b>



Responsive to communication(s) filed on May 28, 1998

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 1-34 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) \_\_\_\_\_ is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims 1-34 are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

## **DETAILED ACTION**

### ***Election/Restriction***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-17, and 30, drawn to an oligonucleotide "corresponding" to the entire untranslated 3' region of a housekeeping gene, and pharmaceutical compositions comprising said oligonucleotides, or antisense thereof, or ribozymes complementary to at least a portion of said UTR, classifiable in class 536, subclass 24.5.
  - II. Claims 18-29, drawn to methods for modulating tumorigenicity by administration of oligonucleotides or ribozymes, classifiable in class 514, subclass 44.
  - III. Claims 21-29, drawn to a method of inhibiting hydroxyurea resistant neoplastic cells or increasing sensitivity of neoplastic cells to chemotherapeutic drugs, by the coadministration of antisense oligonucleotides and a chemotherapeutic drug, classifiable in class 514, subclass 44.
  - IV. Claim 32, drawn to an antibody directed against the oligonucleotide corresponding to the R1 or R2 component of ribonucleotide reductase, classifiable in class 424, subclass 130.1
  - V. Claim 33 and 34, drawn to a method for identifying a substance that binds to an oligonucleotide to modulate tumorigenicity or screening for an agonist or

antagonist of the binding of an oligonucleotide and a substance, classifiable in class 435, subclass 6.

2. The inventions are distinct, each from the other because of the following reasons:
3. Inventions of Group I and the invention of Group IV are unrelated, each from the other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of Group I, drawn to oligonucleotides, antisense oligonucleotides and ribozymes, are nucleic acids that have a different molecular structure and have different operations, functions and effects from the antibodies of Group IV.
4. Inventions of Groups II, III, and V are unrelated, each from the other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of Group II, drawn to methods for modulating tumorigenicity by administration of oligonucleotides, antisense oligonucleotides or ribozymes, the method of Group III, drawn to inhibiting hydroxyurea resistance or increasing sensitivity to hydroxyurea by oligonucleotides, antisense oligonucleotides or ribozymes, and the method of Group V for identifying a substance that binds to an oligonucleotide to modulate tumorigenicity or screening for an agonist or antagonist of the binding of said oligonucleotide and said substance, each have effects and functions that are different from one another.

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5. Inventions of Group I and inventions of Groups II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the oligonucleotides, antisense oligonucleotide, ribozymes, and pharmaceutical compositions thereof of Group I can be used for identifying compounds that bind to an oligonucleotide or antagonists and agonists that modulate that bind to an oligonucleotide, which are materially different processes from the methods of inhibiting tumorigenicity or modulating hydroxyurea resistance.

6. Inventions of Group I and inventions of Groups V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the oligonucleotides, antisense oligonucleotide, ribozymes, and pharmaceutical compositions thereof of Group I can be used in the methods of inhibiting tumorigenicity or modulating hydroxyurea resistance, which are materially different processes from the methods for identifying compounds that bind to an oligonucleotide or antagonists and agonists that modulate that bind to an oligonucleotide.

7. Inventions of Group IV and the inventions of Groups II, III, and V are unrelated, each from the other. Inventions are unrelated if it can be shown that they are not disclosed as capable

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of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antibodies of Group IV, could not be used in the nucleic acid based methods of Groups II, III, and V.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mark L. Shibuya (SRC), Ph.D.*, whose telephone number is (703) 308-9355.

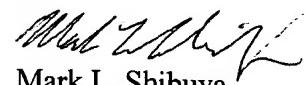
12. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *George Elliott, Ph.D.* may be reached at (703) 308-4003.

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13. Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is (703) 308-0196.



Mark L. Shibuya  
Patent Examiner  
Technical Center 1600  
June 3, 2000